

REMARKS

Upon entry of the above amendment, claims 3-8, 10 and 13-14 will be pending in the captioned application. The amendments do not introduce new matter within the meaning of 35 U.S.C. §132. Accordingly, entry of the amendment is respectfully requested.

1. Rejection of Claims 1-8, 10 and 12-14 under 35 U.S.C. §112, 1st paragraph

The Official Action states that claims 1-8, 10 and 12-14 are rejected under 35 U.S.C. §112, 1st paragraph for lack of enablement. In particular, the Official Action states that “applicants scope of compounds is in the hundreds and applicants have shown some activity of only 12 compounds (and) pharmaceutical activity is highly unpredictable”. The Official Action further states on page 4 (and on page 6) that the specification, while enabling for making salts of the claimed compounds, does not reasonably provide enablement for making solvates and hydrates of the claimed compounds nor the hydrates of the salt or solvates of the salts.”

RESPONSE

Applicants respectfully traverse this rejection.

First, applicants respectfully note that claims 1-2 and 12 have been cancelled without prejudice or disclaimer, rendering the rejection of these claims moot.

Also, applicants note that claims 3-8, 10 and 13-14 have been amended by deleting the claim language directed to hydrates, solvates, hydrates of the salts,

solvates of the salts, N-oxides and the salts of the N-oxides, rendering this part of the rejection moot.

Regarding the other rejection of pending claims 3-8, 10 and 13-14, applicants point out to the Examiner that the rejected claims have been amended to encompass a much narrower genus of compounds than previously claimed. In particular, applicants have cancelled claims 1-2 without prejudice or disclaimer, rendering the broadest compound claim to be claim 3. As such, the genus' substituents have been amended as follows:

The broadest compound claim (claim 3) recites R1 = methyl, whereas cancelled claim 1 recited R1 = 1-4C-alkyl.

Similarly, claim 3 recites R2 = 1-4C-alkoxy, whereas cancelled claim 1 recited R2 = hydroxyl, 1-4C-alkoxy, 3-7C-cycloalkoxy, 3-7C-cycloalkylmethoxy, or 1-4C-alkoxy which is completely or predominantly substituted by fluorine.

Claim 3 recites R3 = 1-4C-alkoxy, whereas cancelled claim 1 recited R3 = hydroxyl, 1-4C-alkoxy, 3-7C-cycloalkoxy, 3-7C-cycloalkylmethoxy, or 1-4C-alkoxy which is completely or predominantly substituted by fluorine.

Cancelled claim 1 also allowed for the possibility that R2 and R3 could together be a 1-2C-alkylenedioxy group. Presently pending claim 3 does not allow for such a possibility.

Further, claim 3 recites R4 = hydrogen, whereas cancelled claim 1 recited R4 = hydrogen, halogen, nitro, 1-4C-alkyl, trifluoromethyl or 1-4C-alkoxy.

Claim 3 recites R5 = 1-4C-alkyl, whereas cancelled claim 1 recited R5 =

hydrogen or 1-8C-alkyl.

Claim 3 recites R6 = hydrogen, 1-4C-alkylcarbonyl, Arylcarbonyl or Aryl-1-2C-alkylcarbonyl, whereas cancelled claim 1 recited hydrogen, 1-8C-alkylcarbonyl, 3-7C-cycloalkylcarbonyl, 3-7C-cycloalkylmethylcarbonyl, Arylcarbonyl, or Aryl-1-4C-alkylcarbonyl.

Further, claim 3 recites R7 = nitro, 1-2C-alkyl or 1-2C-alkoxy, whereas cancelled claim 1 recited R7 = halogen, nitro, 1-4C-alkyl or 1-4C-alkoxy.

Accordingly, applicants have significantly reduced the scope of the broadest compound claim. Each of the Example compounds fall within the scope of this narrower sub-genus of cancelled claim 1, now presently pending claim 3. Each of the Example compounds tested (see Table 1 on page 29) exhibited PDE3 and PDE4 – inhibitory activity.

As such, these amended claims are clearly enabled by the instant specification because applicant has demonstrated a nexus between 1) the effectiveness of these compounds of formula I to inhibit PDE 3 and 4 and 2) the common knowledge in the art that PDE inhibition is useful in treating diverse inflammatory diseases including airway disorders and dermatoses. As stated in the previous Response, the present specification contains references to publications demonstrating this relationship on page 27.

Again, the instant specification contains data on page 29 which clearly demonstrates that the presently claimed compounds inhibit PDE3 and PDE4. Further, it is well known in the art that the inhibition of PDE3 and PDE4 and treatment of diverse

inflammatory diseases, as presently claimed, are related.

In this regard, applicants note that the broadest method claim (claim 12) has also been cancelled without prejudice. Further, claim 13 has been amended to recite very specific airway disorders of interest.

Accordingly, a person of ordinary skill in the art would be enabled by the instant specification, combined with the common knowledge in the art, to practice the presently claimed invention.

Given the extent of applicants' amendments to the claims, applicants respectfully point out that if the enablement rejection of the Examiner is upheld, it would mean that an inventor of an innovative new drug would have to wait to file her patent application until human clinical trials were performed. Such a conclusion is obviously incorrect. A reasonable correlation between a compound's activity and its asserted use, as demonstrated by applicant with the data contained in the specification and the literature references filed with the last Response, is clearly enough to properly demonstrate enablement of the presently claimed methods.

Accordingly, claims 3-8, 10 and 13-14 comply with the requirements of 35 U.S.C. §112, 1st paragraph. As such, applicant respectfully requests that the Examiner reconsider and withdraw this rejection of claim 3-8, 10, and 13-14.

CONCLUSION

In view of the foregoing, applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 3-8, 10, and 13-14 and to allow all of the claims pending in this application to proceed to grant.

If the Examiner has any questions or wishes to discuss this matter, she is welcomed to telephone the undersigned attorney.

Respectfully submitted,

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